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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,537	Applicant(s) MORTON ET AL.
	Examiner Jonathan ML Foreman	Art Unit 3736

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16,26,27 and 29-33* is/are rejected.

7)☒ Claim(s) *2,3,17-25 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 5/14/02 and 1/21/03 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 9, 10, 14 and 31 – 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 2,542,505 to Gascoigne.

In reference to claims 1, 9, 10, 14 and 31 – 33, Gascoigne discloses an adjustable support (Col. 2, lines 50 – 55) defining a concavity (Col. 1, line 56 – Col. 2, line 5). Gascoigne discloses inflatable bladders (A, B) within the concavity; a vacuum source in communication with the concavity; and a pressure source in communication with the bladders (Col. 3, lines 16 – 42). Gascoigne discloses a control for alternately inflating and deflating the bladders in accordance with a predetermined program (Col. 3, lines 43 – 52)

3. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,049,126 to Larsson.

In reference to claim 16, Larsson discloses a frame (3); at least one support (2) on the frame, having a first side for facing in the direction of a patient in use; a movable wall (10) in between the support and the patient in use; and a disposable patient interface (4) positioned between the movable wall and the patient, for contacting the patient when in use.

4. Claims 1, 9, 10, 14 and 31 – 33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,273,868 to Nordvik.

In reference to claims 1, 9, 10, 14 and 31 – 33, Nordvik discloses a support (1) defining a concavity (Col. 4 lines 52 – 54)). The support is adjustable in that the user can position the support in any her breast in any comfortable manner. Nordvik discloses inflatable bladders (4, 6) within the concavity; a vacuum source in communication with the concavity (Col. 5, lines 41 – 43); and a pressure source in communication with the bladders (Col. 5, line 52 – Col. 6, line 4). Nordvik discloses a control for alternately inflating and deflating the bladders in accordance with a predetermined program (Col. 5, lines 23 - 27).

5. Claims 1, 9, 10, 14 and 31 - 33 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,663,587 to Silver et al.

In regards to claims 1, 9, 10, 14 and 31 - 33, Silver et al. discloses a support (142, 143) having a concave side (146); a plurality of inflatable bladders carried on the concave side; a vacuum source in communication with the concave side (Col. 13, lines 21 – 23) and a pressure source in communication with the bladders (Col. 13, lines 18 – 20). Silver et al. discloses a controller for automatically controlling the pressure source. The support comprises a plurality of movable components (142, 143).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,542,505 to Gascoigne as applied to claim 1 above and further in view of U.S. Patent No. 6,358,226 to Ryan.

In regards to claims 4 – 7, Gascoigne discloses a nipple aspiration device having a fluid circulation pathway for circulating fluid through inflatable bladders (A, B), but fails to disclose a heat source in thermally conductive contact with the fluid to heat the bladders. Ryan discloses a nipple aspiration device (Figure 1) having a heat source in thermally conductive contact with the fluid of an inflatable bladder (Co. 4, lines 27 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Gascoigne to include a heat source in thermally conductive contact with the fluid as taught by Ryan to raise the mammary gland to a temperature that makes milk withdrawal more comfortable (See Abstract).

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,542,505 to Gascoigne in view of U.S. Patent No. 6,358,226 to Ryan as applied to the claim 6 above, and further in view of U.S. Patent No. 6,273,868 to Nordvik.

In reference to claim 8, Gascoigne in view of Ryan discloses inflatable bladders (A, B), but fails to disclose at least three inflatable bladders. Nordvik discloses a nipple aspiration device (Figure 3) having at least three inflatable bladders (13 – 15). It would have been obvious to modify

the device as disclosed by Gascoigne in view of Ryan to include at least three inflatable bladders as taught by Nordvik in order to generate a pulsating wave towards the nipple (Col. 6, lines 56 – 60). Furthermore, duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

9. Claims 11 – 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,273,868 to Nordvik.

In reference to claims 11 – 13, Nordvik discloses a predetermined program controlling the inflation of the bladder (Col. 5, lines 25 – 28). The program is adjusted by the user. Nordvik discloses the program inflating the bladder in the range of 60 to 120 cycles per minute (Col. 5, lines 50 – 51). Nordvik does not disclose the program inflating the bladder in the range of 2 to 40 cycles per minute. However, where a change in size or range of a prior art reference merely represents a change of degree, and not a change of kind, such change is a design consideration within the skill of the art. ***In re Aller***, 220 F.2d 454, 105 USPQ 233 (CCPA 1955).

In reference to claim 15, Nordvik discloses an inflatable bladder but fails to disclose the maximum thickness of the inflated profile being in the range of 0.2 to 2.0 inches. However, a change in the size of a prior art device is a design consideration within the skill of the art. ***In re Rose***, 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

10. Claims 16, 26, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,542,505 to Gascoigne in view of U.S. Patent No. 6,579,258 to Atkin et al.

In regards to claims 16, 26, 27 and 29, Gascoigne discloses a device for obtaining intraductal fluid from a breast having a frame; a support (Col. 2, lines 50 – 55) on the frame having a first side facing a patient; a movable wall (18) positioned in between the support and the patient. However, Gascoigne fails to disclose a disposable interface positioned between the movable wall and the

patient. Gascoigne fails to disclose the interface being a flexible membrane with a proximal end with a first diameter and a distal end with a second, larger diameter. Atkin et al. teaches a disposable interface (5) for obtaining intraductal fluid from a breast being a flexible membrane with a proximal end with a first diameter (7) and a distal end with a second, larger diameter (6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Gascoigne to include a disposable interface as taught by Atkin et al. to further enhance the peristaltic pressure applied to the nipple and areola (Abstract). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,542,505 to Gascoigne in view of U.S. Patent No. 6,579,258 to Atkin et al. as applied to claim 16 above, and further in view of U.S. Patent No. 6,358,226 to Ryan.

In regards to claim 30, Gascoigne discloses a nipple aspiration device having a fluid circulation pathway for circulating fluid to the movable wall (18), but fails to disclose a heat source in thermally conductive contact with the fluid. Ryan discloses a nipple aspiration device (Figure 1) having a heat source in thermally conductive contact with the fluid of an inflatable bladder (Co. 4, lines 27 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Gascoigne in view of Atkin et al. to include a heat source in thermally conductive contact with the fluid as taught by Ryan to raise the mammary gland to a temperature that makes milk withdrawal more comfortable (See Abstract).

Allowable Subject Matter

12. Claims 2, 3, 17 – 25 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

JMLF
January 25, 2004

CHARLES MARMOR
PRIMARY EXAMINER